

## **REMARKS**

Claims 1-3, 8-10, 12, 14, 20-21, and 23 are currently pending in this application. Claims 4, 6-7, 11, 13, 15, 17-19, 22, 25-27 have been withdrawn from consideration. Each of the pending claims stands rejected.

### **Interview Summary**

A telephonic interview was conducted with the Examiner on August 3, 2004. Discussions during this telephonic interview addressed: (1) the resubmission of paperwork relating to the PTO-1149 form; (2) the new matter rejection of Figure 5; and (3) the withdrawal of claims by the Office action.

As to no. 1, the Examiner indicated that the PTO-1449 form was missing from the file and the undersigned agreed to resubmit the missing paperwork.

As to nos. 2 and 3, no conclusion was reached for the new matter rejection of Figure 5 or for the withdrawal of claims. A petition is being filed regarding the withdrawal of claims and the rejection of Figure 5 is addressed below.

Substantive arguments regarding the §102(b) and §103(a) rejections from the June 15, 2004 Office action were not discussed.

### **Information Disclosure Statement**

The Office action requests the undersigned resubmit PTO-1149 form, which was originally submitted on April 4, 2003. The undersigned has appended the PTO-1149 form, the patents listed on the form, and a photocopy of the postcard indicating that the requested paperwork was originally submitted on April 4, 2003. The undersigned has also included a photocopy of the postcard indicating that this paperwork was previously submitted on December 2, 2003. Acknowledgement that this material was received and considered is requested.

### **37 C.F.R. §1.83(a) Drawing Objection**

“[I]nformation contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.” MPEP §2163.06. Moreover, “the drawings and the specification may be amended to

conform to each other and ... the added matter will not be deemed technical 'new matter' within the prohibition of the law." *In re Heinle*, 52 C.C.P.A. 1164, 1173 (1965).

In this case, the drawing correction of November 25, 2002, has been disapproved for the alleged introduction of new matter. However, the modifications to Fig. 5 do not introduce new matter as the updates simply correlate the drawings with the specification. Support for the objected to grooves on the hyper-deformable balloon can be found in paragraph [0025] of the specifications, which states that "the balloon may be internally ribbed or notched or otherwise specifically configured to increase its deformability...." Furthermore, as previously explained in the Response to the September 10, 2003, Office action, ribbed is defined as "to make with ridges or raised markings," and ridge is defined as a "raised narrow strip." Thus, using these definitions and the other disclosures in the specification, the undersigned submits that one skilled in the art would understand that the specification provides clear support for amended Figure 5.

Figure 16 has been amended herein in response to the Office action's assertion that "the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown...." The undersigned submits that amended Figure 16, enclosed herein, which now shows the grooves in the first balloon, is not new matter at least for the above reason.

### **Objections to Claims 2-3**

Claim 2 and 3 stand objected to as allegedly failing to further limit the invention. The undersigned requests reconsideration because there are patentable distinctions between these claims.

For one, Claim 2 recites that the "exterior surface of the first inflatable balloon is contacting a therapeutic." This is different than claim 1, which recites "the exterior surface of the first inflatable balloon at least partially covered with a therapeutic." Thus, claim 2 requires contact while claim 1 simply recites covering, which may or may not result in contact.

For another, Claim 3 recites "a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon." There is no such source anywhere in claim 1.

**35 U.S.C. § 102(b) Rejection**

Claims 1-3, 8-10, 20-21, and 23 were rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (U.S. Pat. No. 5,295,962). The undersigned submits that Crocker does not disclose or suggest an inflatable balloon wherein “the exterior surface of the first inflatable balloon ... [is] covered with a therapeutic when the first inflatable balloon is in an initial unexpanded state,” as in claim 1. The Office action presumes that “Crocker’s device is capable [of] releasing the drug through the pores in an unexpanded state.” However, Crocker states that “[t]he inflated volume of inflation balloon 30 causes the drug to be expelled by way of ports 40 outside of the drug delivery system.” Col. 7, lines 43-45. Hence, Crocker requires the therapeutic to be squeezed out of the balloon during or after inflation in order for the therapeutic to reach the exterior of the balloon. Therapeutic is, therefore, not present in an initial unexpanded state as recited in the claim. For at least this reason, Crocker does not anticipate the claims.

Consistent with the above, the undersigned also submits that Crocker does not disclose or suggest “inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic” as substantially recited in claim 20. For at least this reason, Crocker does not anticipate claims 20-21 and 23.

**35 U.S.C. § 103(a) Rejection**

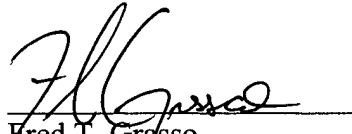
Claims 1-3, 8-10, 12, 14, 20-21 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brown et al. (US Pat. No. 6,471,672) or Abele et al. (US Pat. No. 5,704,913) in view of Sahatjian (US Pat. No. 5,304,121). The undersigned submits that none of these references disclose or suggest “the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder,” as substantially recited in claims 1 and 20. As these references do not disclose or suggest this language, there is no need to address the impropriety of combining the references.

## CONCLUSION

The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

Respectfully submitted,

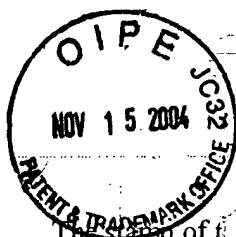
Date: November 12, 2004

  
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**In the Drawings:**

Please replace figure 16 with amended figure 16, which is attached.



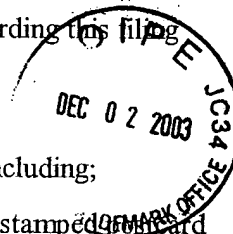
The receipt of the Patent Office hereon may be taken as acknowledging the receipt, on the date stamped, of

INVENTOR: Maria PALASIS  
APPLICATION NO. : 09/760,807  
FILED: January 17, 2001  
TITLE: THERAPEUTIC DELIVERY BALLOON  
GROUP ART UNIT: 3763

The PTO is authorized to charge or credit any fees regarding this filing to Deposit Account No. 11-0600.

**PAPERS FILED:**

1. Response to the September 10, 2003 Office Action including;
2. Fig. 16 (one sheet)
3. Information Disclosure Statement dated 4/4/03 with stamped front card



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